K112761

APR 25 2012

ZOLL Medical Corporation
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824
U.S.A

510(k) Summary:

Submitter's Name and Address:

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105
(978) 421-9655

Contact Person:

Chuck Kolifrath
(978) 421-9786

Date Summary Prepared:

September 16, 2011

Device:

ZOLL Propaq MD

Classification: Class III

Automated External Defibrillators (MKJ)
Cardiopulmonary Resuscitation Aid (LIX)
Low-Energy – Defibrillators (LDD)
Cardiac Monitors – including Cardiotachometer and Rate Alarms (DRT)
External Transcutaneous Cardiac Non-Invasive Pacemaker (DRO)
Noninvasive Blood Pressure Measurement System (DXN)
Blood Pressure Computer (DSK)
Carbon Dioxide Gas Analyzer (CCK)
Oximeter (DQA)

Description:

The ZOLL Propaq MD device (reviewed and cleared by the agency under application K100654) is being revised with additional software features. The Propaq MD is a light weight, portable device designed to be used by trained medical personnel who are familiar with basic monitoring, vital sign assessment and emergency cardiac care. As in its previous configuration, the Propaq MD combines the functions of an ECG monitor, manual defibrillator, external transcutaneous pacer, pulse oximeter, non-invasive blood pressure monitor, invasive pressure monitor, respiration rate monitor and temperature monitor. Functions are offered as options and functions can be configured to meet the needs of a particular application.

Additionally, the proposed configuration adds the following features:

- Semi-automatic external defibrillation function (AED) Mode
- Inovise Audicor 12-Lead ECG Interpretive Algorithm
- ECG Life Threatening Alarms
- Expanded Data Logging capabilities

Indications for Use:

The Propaq MD is intended for use by trained medical personnel who are familiar with basic monitoring, vital sign assessment, emergency cardiac care and the use of the Propaq MD. The Propaq MD is also intended for use by (or on the order of) physicians at the scene of an emergency or in a hospital emergency room, intensive care unit, cardiac care unit, or other similar areas of a hospital. The usage may be in an ambulance or at the scene of an emergency. It is also intended to be used during the transport of patients. The Propaq MD will be used primarily on patients experiencing symptoms of cardiac arrest or in post trauma situation. It may also be used whenever it is required to monitor any of those functions that are included (as options) in the device. The Propaq MD can be used on pediatric patients (as described in the following table) and on adult patients (21 years of age or older) with and without heart dysfunction.

Pediatric Subpopulation	**Approx. Age Range**
Newborn (neonate)	Birth to 1 month of age
Infant	1 month to 2 years of age
Child	2 to 12 years of age
Adolescent	12-21 years of age

When the pediatric patient is less than 8 years of age or weighs less than 55 lbs. (25 kg.), use ZOLL ***pedi·padz***® pediatric defibrillation electrodes. Do not delay therapy to determine the patient's exact age or weight.

The following indications for use are identical to the previous configuration of the Propaq MD (reviewed and cleared by the FDA under application K100654):

Manual Defibrillation

Use of the Propaq MD in the manual mode for external and internal defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness
- Absence of breathing
- Absence of pulse.

This product should be used only by qualified medical personnel for converting ventricular fibrillation and rapid ventricular tachycardia to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats.

The unit can also be used for synchronized cardioversion of certain atrial or ventricular arrhythmias. Qualified medical personnel must decide when synchronized cardioversion is appropriate.

The patient population will range from newborn (neonate) to adult.

ECG Monitoring

The Propaq MD is intended for use to monitor and/or record 3, 5, 12-Lead ECG waveform and heart rate, and to alarm when heart rate is above or below limits set by the operator. The patient population will range from newborn (neonate) to adult, with and without heart dysfunction.

External Transcutaneous Pacing

This product can be used for temporary external cardiac pacing in conscious or unconscious patients as an alternative to endocardial stimulation.

The purposes of pacing include:

- **Resuscitation from standstill or bradycardia of any etiology:**

  Noninvasive pacing has been used for resuscitation from cardiac standstill, reflex vagal standstill, drug induced standstill (due to procainamide, quinidline, digitalis, b- blockers, verapamil, etc.) and unexpected circulatory arrest (due to anesthesia, surgery, angiography, and other therapeutic or diagnostic procedures). It has also been used for temporary acceleration of bradycardia in Stokes- Adams disease and sick-sinus syndrome. It is safer, more reliable, and more rapidly applied in an emergency than endocardial or other temporary electrodes.

- **As a standby when standstill or bradycardia might be expected:**

Noninvasive pacing may be useful as a standby when cardiac arrest or symptomatic bradycardia might be expected due to acute myocardial infarction, drug toxicity, anesthesia or surgery. It is also useful as a temporary treatment in patients awaiting pacemaker implants or the introduction of transvenous therapy. In standby pacing applications, noninvasive pacing may provide an alternative to transvenous therapy that avoids the risks of displacement, infection, hemorrhage, embolization, perforation, phlebitis and mechanical or electrical stimulation of ventricular tachycardia or fibrillation associated with endocardial pacing.

- **Suppression of tachycardia:**

  Increased heart rates in response to external pacing often suppress ventricular ectopic activity and may prevent tachycardia.

- **Pediatric Pacing:**

  Pacing can be performed on pediatric patients weighing 33 lbs. (15kg) or less using ZOLL pediatric hands-free therapy electrode pads. Prolonged pacing (in excess of 30 minutes), particularly in neonates, could cause burns. Periodic inspection of the underlying skin is recommended.

Non-Invasive Blood Pressure Monitoring

The Propaq MD is intended for use to make non-invasive measurements of arterial pressure and heart rate, and to alarm if either parameter is outside of the limits set by the user. Measurements are made using an inflatable cuff on the patient's arm or leg. The patient population will range from newborn (neonate) to adult.

Temperature Monitoring

The Propaq MD is intended for use to make continuous temperature measurements of rectal, esophageal, or surface temperatures, and to alarm if the temperature is outside of the limits set by the user. The patient population will range from newborn (neonate) to adult.

SpO2 Monitoring

The Propaq MD is intended for use to monitor pulse rate and oxygen saturation of arteriolar hemoglobin, and to alarm if either parameter is outside of the limits set by the user. Measurements are made non-invasively at remote sites such as a finger, toe, ear lobe, bridge of nose, etc. The patient population will range from newborn (neonate) to adult.

Respiration Monitoring

The Propaq MD is intended for use to continuously monitor respiration rate and to alarm if the rate falls outside of the range set by the operator. Because the measurement method actually measures respiratory effort, apnea episodes with continued respiratory effort (such as obstructive apnea) may not be detected. It is not intended to be used as an apnea monitor. The patient population will range from newborn (neonate) to adult.

CO2 Monitoring

The Propaq MD is intended for use to make continuous noninvasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate. The patient population will range from newborn (neonate) to adult.

Invasive Pressure Monitoring

The Propaq MD is intended for use to display and make continuous invasive pressure measurements from any compatible pressure transducer. The primary intended uses are arterial blood pressure, central venous pressure and intracranial pressure monitoring. Any contra-indications of the particular transducer selected by the user shall apply. The patient population will range from newborn (neonate) to adult.

The following indications for use represent additional features being added in the proposed Propaq MD configuration:

Semiautomatic Operation (AED)

The Propaq MD products are designed for use by emergency care personnel who have completed training and certification requirements applicable to the use of a defibrillator where the device operator controls delivery of shocks to the patient.

They are specifically designed for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care are incorporated into a medically-approved patient care protocol.

Use of the Propaq MD in the Semiautomatic mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness.
- Absence of breathing.
- Absence of pulse.

When the patient is less than 8 years of age or weighs less that 55 lbs. (25 Kg), use ZOLL pediatric defibrillation electrodes. Do not delay therapy to determine patient's exact age or weight.

12-Lead Analysis

The 12-lead ECG Analysis is intended for use in acquiring, analyzing and reporting ECG data, and to provide interpretation of the data for consideration by caregivers. The interpretations of ECG data offered by the device are only significant when used in conjunction with caregiver overread as well as consideration of all other relevant patient data. The 12-lead ECG Analysis is intended for use on adults (> 18 years of age).

Substantial Equivalence:

The proposed ZOLL Propaq MD is substantially equivalent to the features and functions of the predicate units: ZOLL Propaq MD (K100654), ZOLL E Series (K072923) and Inovise Audicor 12-lead Interpretive algorithm (K032145).

Comparison of Technological Characteristics

The proposed ZOLL Propaq MD utilizes the same features and functions as the indicated predicate devices: ZOLL Propaq MD (K100654), ZOLL E Series (K072923) and Inovise Audicor 12-lead Interpretive algorithm (K032145).

Performance Testing:

Extensive performance testing ensures that the proposed ZOLL Propaq MD performs as well as the indicated predicate devices and meets all of its functional requirements and performance specifications. Safety testing assures that the device complies with applicable sections of recognized industry and safety standards.

Conclusion

The information provided in this 510(k) demonstrates that the features and functions of the proposed ZOLL Propaq MD are substantially equivalent to those of the indicated commercially distributed devices with regard to performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 25 2012

Zoll Medical Corporation
c/o Mr. Charles W. Kolifrath
Regulatory Affairs Manager
269 Mill Road
Chelmsford, MA 01824

Re: K112761
Trade/Device Name: ZOLL Propaq MD
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ, LIX, LDD, DRT, DRO, DXN, DSK, CCK, and DQA
Dated: April 20, 2012
Received: April 23, 2012

Dear Mr. Kolifrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: **Propaq MD**

Intended Use:

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- Absence of breathing
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This product should be used only by qualified medical personnel for converting ventricular

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112761

fibrillation and rapid ventricular tachycardia to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats.

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